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RD2010-01

## Registration Decision

# Diallyl Disulfide and Related Sulfides

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## Registration Decision for Diallyl Disulfide and Related Sulfides

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of DADS Technical (Registration Number 29332) and DADS (Registration Number 29333), a fungicide containing diallyl disulfide and related sulfides, which suppresses white rot (*Sclerotium cepivorum*) disease on onion and other bulb vegetables.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2009-12, *Diallyl Disulfide and Related Sulfides*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for Diallyl Disulfide and Related Sulfides and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-12. This decision is consistent with the proposed registration decision stated in PRD2009-12.

For more details on the information presented in this Registration Decision, please refer to the PRD2009-12 that contains a detailed evaluation of the information submitted in support of this registration.

### What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>3</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value<sup>4</sup> when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

<sup>3</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>4</sup> "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

## **What Is Diallyl Disulfide and Related Sulfides?**

Diallyl disulphide and related sulfides are the active ingredients in the end-use product DADS fungicide, which is based on a natural metabolite of garlic. DADS fungicide suppresses white rot (*Sclerotium cepivorum* Berk.) disease on onion and other bulb vegetables, by reducing the level of *Sclerotium cepivorum* inoculum in the soil in the absence of a host crop.

## **Health Considerations**

### **Can Approved Use of Diallyl Disulfide and Related Sulfides Affect Human Health?**

Diallyl disulfide and related sulfides are unlikely to affect human health when used according to label directions.

Exposure to diallyl disulfide and related sulfides may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur; and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, diallyl disulfide and related sulfides, is highly acutely toxic by the oral route, slightly acutely toxic by the dermal route, minimally irritating to eyes, severely irritating to skin, a skin sensitizer, not a mutagen, and a respiratory irritant.

Due to the toxic and irritative potential of diallyl disulfide and related sulfides, the principal display panels of the DADS Technical and DADS end-use product labels are required to state: "DANGER (PICTOGRAM) POISON", "DANGER - SKIN IRRITANT", "POTENTIAL SKIN SENSITIZER", and "Contains garlic allergen."

In addition, the principal display panels of the technical and end-use product labels are required to have the statements: "Prevent access by unauthorized personnel" and "Keep out of reach of children and prevent access by unauthorized personnel" respectively.

The "PRECAUTIONS" section on the secondary display panels of both the labels are required to include: "DO NOT use if allergic to garlic. Fatal or poisonous if swallowed. May be harmful if absorbed through the skin. Harmful if inhaled. Avoid inhaling/breathing vapours or fumes. May irritate eyes. Avoid contact with eyes. Severely irritating to the skin. DO NOT get on skin. Potential skin sensitizer. Avoid contact with clothing."

These cautionary statements are considered to be sufficient to minimize any human health and safety concerns.

Waivers were granted for short-term toxicity, reproduction and developmental toxicity, and genotoxicity studies based on the end-use product proposed use pattern, method of application and the anticipated low potential for exposure when applied as directed.

### **Residues in Water and Food**

Dietary risks from food and water are not of concern.

Diallyl disulfide and related sulfides are not applied directly to food or feed crops. Dietary risk to humans is considered negligible based on the intended use, method of application, and low application rate.

Diallyl disulfide and related sulfides are non-persistent in the environment (half life <4 hours in water/soil); therefore, crops planted three months after the application of diallyl disulfide and related sulfides are unlikely to result in food residues.

### **Occupational Risks From Handling Diallyl Disulfide and Related Sulfides**

Occupational risks are not of concern when diallyl disulfide and related sulfides are used according to label directions, which include protective measures.

Occupational exposure to diallyl disulfide and related sulfides is expected to be negligible as the proposed method of application is by direct injection into the soil column at a low application rate (2%), and the treated soil is to be packed immediately with a mechanical packer.

Precautionary statements on the label (for example, wearing of personal protective equipment) are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

## **Environmental Considerations**

### **What Happens When Diallyl Sulfides and Related Sulfides are Introduced into the Environment?**

Diallyl disulfide and related sulfides are naturally occurring compounds found in *Allium* crops. From the proposed use pattern, negligible diallyl disulfide and related sulfides will enter the environment as compared to agricultural sources such as fields planted with garlic and onions.

Diallyl disulfide and related sulfides are soluble in water and have low mobility in soil. Due to their high volatility, diallyl disulfide and related sulfides are non-persistent in terrestrial and aquatic environments. Diallyl disulfide and related sulfides are expected to volatilize from dry, wet or moist surfaces; the vapor-phase diallyl disulfides are expected to be readily degraded in the atmosphere by reactions with photochemically produced hydroxyl radicals.

Diallyl disulfide and related sulfides are expected to pose negligible risk to terrestrial and aquatic organisms under conditions of use.

## **Value Considerations**

### **What Is the Value of DADS fungicide?**

There is currently only one other product available to growers for the management of white rot disease on garlic and onions. The registration of DADS fungicide will provide growers with another alternative. In addition, diallyl disulfide and related sulfides represent a new mode of action for the suppression of the disease, which is unlikely to lead to resistance development in the pathogen population, based on the mode of action and method of use.

## **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of DADS to address the potential risks identified in this assessment are as follows.

## **Key Risk-Reduction Measures**

### **Human Health**

In order to mitigate the inappropriate use of the product and help avoid accidental exposure, the principal display panels of the DADS Technical and end-use product labels are required to have the statements, "Prevent access by unauthorized personnel" and "Keep out of reach of children and prevent access by unauthorized personnel", respectively.

Because there is a concern for potential inhalation exposure during loading or when handling the concentrated end-use product (90% w/w, active ingredient), workers must use a NIOSH/MSHA approved supplied-air respirator during those activities.

The personal protective equipment proposed on the end-use product label includes the NIOSH/MSHA approved supplied-air respirator during clean-up in case of spill or leak and during clean-up and repair activities, chemical goggles for eye protection and the wearing of rubber or neoprene gloves and a protective garment to prevent skin contact. The label also states that the product is not to be applied to the soil surface, the treated surface area is to be sealed using a mechanical packer immediately after application, and the treated soil is not to be disturbed for 90 days after sealing.

### **Environment**

Risk to non-target organisms will be mitigated by appropriate label precautions.

### **Other Information**

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)).

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website under Request a Reconsideration of Decision ([www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd](http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd)) or contact the PMRA's Pest Management Information Service.

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<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.





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